DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-000

August 19, 2014

CIDEN Technologies, LLC
c/o Courtney Clark, CBA, RAC
Regulatory Affairs Manager of Submissions
Sybron Dental Specialties
1717 W. Collins Ave
Orange, CA 92867

Re: K140703
Trade/Device Name: OPA 30 Solution
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid chemical sterilant/high level disinfectants
Regulatory Class: II
Product Code: MED
Dated: July 22, 2014
Received: July 23, 2014

Dear Ms. Clark,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140703

Device Name
OPA 30 Solution

Indications for Use *(Describe)*
OPA 30 Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. OPA 30 Solution may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Opaciden OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20°C (68°F), for a reuse period not to exceed 30 days. OPA 30 Solution may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C), at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with an immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. 510(k) SUMMARY
for
OPA 30 Solution (K140703)

1. Submitter Information**:**

Ciden Technologies, LLC
360 Cold Spring Avenue
West Springfield, MA 01089

Contact Person: Courtney Clark
Telephone Number: 714-516-7426
Fax Number: 714-516-7472

Date Prepared: 22 July 2014

2. Device Name:

Proprietary Name:	OPA 30 Solution
Classification Name:	Liquid chemical germicide/high level disinfectant
CFR Number:	21 CFR 880.6885
Device Class:	II
Product Code:	MED
FDA review panel code:	INCB

3. Predicate Device:

The legally marketed predicate device is Opaciden® Solution (K070627), Product Code MED, manufactured by Ciden Technologies LLC and determined to be substantially equivalent to a legally marketed device on August 2, 2007.

4. Description of Device:

The OPA 30 Solution is a clear, pale blue liquid with a pH of 7.5. It contains 0.60% *ortho*-Phthalaldehyde in an aqueous base containing buffers, chelating agents and a corrosion inhibitor. It is stable at 15-30° C (59-86° F) for its labeled shelf life of 24 months. OPA 30 Solution may be used or reused for manual (up to 30 days) or automated reprocessing (up to 14 days), according to the Directions for Use. OPA 30 Solution must be used at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with the immersion time and temperature specified for the disinfection method.

5. Statement of Intended Use:

OPA 30 Solution is a high level disinfectant for reprocessing heat-sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. OPA 30 Solution may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Opaciden OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20° C (68° F), for a reuse period not to exceed 30 days. OPA 30 Solution may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C), at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with an

immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The chemical formulation and technical characteristics of the proposed OPA 30 Solution are identical to those of the predicate Opaciden® Solution (K070627). The indications for use, material compatibility and shelf life have been expanded for the proposed OPA 30 Solution due to the results of additional performance testing. There are no substantial technical or functional differences between the proposed OPA 30 Solution and the predicate (K070627) device. Based on this information and the results of the performance testing, it is expected that the proposed OPA 30 Solution will be as safe and effective as the predicate Opaciden® Solution (K070627) when used as directed.

Device Comparison Table

ELEMENT	**PREDICATE DEVICE: Opaciden® Solution (K070627)**	**PROPOSED DEVICE: OPA 30 Solution**
CLASSIFICATION NAME (CFR; Product code)	Liquid chemical germicide/high level disinfectant (21 CFR § 880.6885, Product Code MED)	Liquid chemical germicide/high level disinfectant (21 CFR § 880.6885, Product Code MED)
INDICATIONS FOR USE	Opaciden® Solution (K070627) is a high level disinfectant for reprocessing heat-sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. Opaciden® Solution may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Opaciden OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20°C (68°F), for a reuse period not to exceed 14 days. Opaciden® Solution may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum 25°C), at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with an immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.	**OPA 30** Solution is a high level disinfectant for reprocessing heat-sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. **OPA 30** Solution may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Opaciden OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20°C (68°F), for a reuse period not to exceed **30** days. **OPA 30** Solution may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C), at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with an immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.
ACTIVE INGREDIENT	*ortho*-Phthalaldehyde 0.60%	*ortho*-Phthalaldehyde 0.60%

ELEMENT	PREDICATE DEVICE: Opaciden® Solution (K070627)	PROPOSED DEVICE: OPA 30 Solution
INERT INGREDIENTS	99.40%	99.40%
PHYSICAL PROPERTIES	Clear, pale blue liquid with a pH of 7.5. Contains 0.60% OPA in an aqueous base containing buffers, chelating agents and a corrosion inhibitor. It is stable at 15-30° C (59-86° F) for its labeled shelf life.	Clear, pale blue liquid with a pH of 7.5. Contains 0.60% OPA in an aqueous base containing buffers, chelating agents and a corrosion inhibitor. It is stable at 15-30° C (59-86° F) for its labeled shelf life.
MINIMUM EFFECTIVE CONCENTRATION (MEC)	0.3%	0.3%
REUSE PERIOD	14 Days Manual, 14 days automated	**30** Days Manual, 14 days automated
MICROBIOLOGY	Effective against:	Effective against:
Vegetative organisms	Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Mycobacterium bovis	Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Mycobacterium bovis
Fungi	Trichophyton mentagrophytes	Trichophyton mentagrophytes
Viruses, non-enveloped	Poliovirus Type 1	Poliovirus Type 1
	Rhinovirus Type 42	Rhinovirus Type 42
	Hepatitis A (AER)	Hepatitis A (AER)
Viruses, enveloped	Avian influenza	Avian influenza
	Hepatitis B	Hepatitis B
	Influenza Type A (Hong Kong)	Influenza Type A (Hong Kong)
	HIV-1	HIV-1
	Herpes simplex Type 1	Herpes simplex Type 1
Spores	Clostridium sporogenes	Clostridium sporogenes
	Bacillus subtilis	Bacillus subtilis
TOXICITY	Positive for acute oral toxicity, moderate skin irritation. Negative for dermal and cytotoxicity. Probable eye irritant.	Positive for acute oral toxicity, moderate skin irritation. Negative for dermal and cytotoxicity. Probable eye irritant.
REUSABLE DEVICE COMPATIBILITY	Olympus and Pentax endoscopes are compatible	Olympus and Pentax endoscopes are compatible
CHEMICAL INDICATOR	Opaciden OPA Reagent Strips	Opaciden OPA Reagent Strips
SHELF LIFE	15 month shelf life for a closed container.	**24** month shelf life for a closed container.
MATERIAL COMPATIBILITY	Materials previously cleared in the predicate Opaciden® Solution (K070627)	Materials previously cleared in the predicate Opaciden® Solution (K070627) and **Acrylonitrile Butadiene Styrene (ABS)**

Non-Clinical Performance Data

The OPA 30 Solution has been tested for stability, re-use for manual processing and material compatibility following:

- Guidance for Industry and FDA Reviewers: "Content and Format of Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/High Level Disinfectants" Section III

Due to the fact that the chemical formulation of the proposed OPA 30 Solution and the predicate Opaciden® Solution (K070627) is identical, additional testing requirements described in the FDA guidance "Content and Format of Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/High Level Disinfectants" have not been repeated. The required testing was previously submitted, reviewed and cleared in K070627. Results for the applicable tests were acceptable and demonstrated performance in accordance with the proposed OPA 30 Solution product labeling.

Clinical Performance Data

There is no clinical data included in this submission.

Conclusion as to Substantial Equivalence

The OPA 30 Solution is as safe, as effective, and performs as well as the predicate Opaciden® Solution (K070627), and is therefore determined to be substantially equivalent to Opaciden® Solution (K070627).